

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ribavirin Solid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Acute toxicity (Oral) : Category 5

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - : Category 3  
single exposure

Specific target organ toxicity - : Category 1 (Blood)  
repeated exposure (Oral)

##### GHS label elements

Hazard pictograms :



Signal word : Danger

---

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

Hazard statements : H303 May be harmful if swallowed.  
H335 May cause respiratory irritation.  
H341 Suspected of causing genetic defects.  
H360Df May damage the unborn child. Suspected of damaging fertility.  
H372 Causes damage to organs (Blood) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P301 + P317 IF SWALLOWED: Get medical help.  
P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell.  
P318 IF exposed or concerned, get medical advice.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Ribavirin	36791-04-5	>= 50 - < 70
Cellulose	9004-34-6	>= 10 - < 20
Magnesium stearate	557-04-0	>= 1 - < 5

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May be harmful if swallowed. May cause respiratory irritation. Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

---

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

---

### 6. ACCIDENTAL RELEASE MEASURES

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air.  
Add excess liquid to allow the material to enter into solution.  
Soak up with inert absorbent material.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

---

### 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

- Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ribavirin	36791-04-5	Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
		TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

#### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

- Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- 

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Colour : white
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : No data available
- Evaporation rate : Not applicable
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : Not applicable
- Relative vapour density : Not applicable
- Relative density : No data available

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

---

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

---

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### **Acute toxicity**

May be harmful if swallowed.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: 2,249 mg/kg  
Method: Calculation method

#### **Components:**

##### **Ribavirin:**

Acute oral toxicity : LD50 (Rat): 4,116 - 5,584 mg/kg

---

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

LD50 (Mouse): > 10,000 mg/kg

LD50 (Dog): >= 1,500 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1,554 - 1,758 mg/kg  
Application Route: Intraperitoneal

LD50 (Mouse): 1,268 mg/kg  
Application Route: Intraperitoneal

### Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

### Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Ribavirin:

Remarks : No data available  
May irritate skin.

#### Magnesium stearate:

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

### Serious eye damage/eye irritation

Not classified based on available information.



## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

### Components:

#### **Ribavirin:**

Remarks : No data available  
May irritate eyes.

#### **Magnesium stearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Ribavirin:**

Remarks : No data available

#### **Magnesium stearate:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

### **Germ cell mutagenicity**

Suspected of causing genetic defects.

### Components:

#### **Ribavirin:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Test system: Rodent cell line  
Result: positive  
  
Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

Genotoxicity in vivo : Test Type: dominant lethal test  
Species: Rat  
Result: negative

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Test Type: Mouse Lymphoma  
Species: Mouse  
Result: positive

Test Type: Micronucleus test  
Species: Mouse  
Result: positive

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

### **Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Ribavirin:**

Species : Mouse  
Application Route : Oral  
Exposure time : 6 Months  
LOAEL : 75 mg/kg body weight  
Result : negative  
Target Organs : Blood, Testes  
Remarks : The mechanism or mode of action may not be relevant in humans.

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 10 mg/kg body weight  
Result : negative  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Mouse  
Application Route : Oral  
Exposure time : 18 Months  
Result : negative  
Remarks : The mechanism or mode of action may not be relevant in humans.

### **Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

### **Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

### **Components:**

#### **Ribavirin:**

Effects on fertility : Test Type: Fertility  
Species: Rat, male  
Application Route: Intraperitoneal injection  
Fertility: LOAEL: < 20 mg/kg body weight  
Symptoms: Reduced fertility  
Result: positive

Test Type: Fertility  
Species: Mouse, male  
Application Route: Oral  
Fertility: LOAEL: 35 mg/kg body weight  
Symptoms: Reduced fertility  
Result: positive

Test Type: Fertility  
Species: Rat, females  
Application Route: Oral  
Fertility: NOAEL: 10 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Test Type: Fertility  
Species: Rat, male

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Application Route: Oral  
Fertility: NOAEL: 160 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Test Type: Development  
Species: Rat, female  
Application Route: Oral  
Developmental Toxicity: LOAEL: <= 1 mg/kg body weight  
Symptoms: Reduced body weight, Reduced number of viable fetuses, Skeletal malformations  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Development  
Species: Rabbit, female  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 1 mg/kg body weight  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Symptoms: Reduced body weight, Skeletal malformations  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Development  
Species: Hamster  
Application Route: Oral  
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight  
Symptoms: Skeletal and visceral variations, Total Resorptions / resorption rate  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 0.3 mg/kg body weight  
Embryo-foetal toxicity: LOAEL: 1 mg/kg body weight  
Symptoms: Skeletal malformations  
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

### **Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **STOT - single exposure**

May cause respiratory irritation.

### **Components:**

#### **Ribavirin:**

Assessment : May cause respiratory irritation.

### **STOT - repeated exposure**

Causes damage to organs (Blood) through prolonged or repeated exposure if swallowed.

### **Components:**

#### **Ribavirin:**

Exposure routes : Ingestion  
Target Organs : Blood  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

### **Components:**

#### **Ribavirin:**

Species : Monkey  
LOAEL : 30 mg/kg  
Exposure time : 10 d  
Target Organs : Blood, Gastrointestinal tract

Species : Rat  
NOAEL : 7.6 mg/kg  
Application Route : Inhalation  
Exposure time : 90 d  
Target Organs : Blood, Lungs

Species : Dog  
NOAEL : 5 mg/kg  
Application Route : Oral

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Exposure time : 1 yr  
Target Organs : Blood, Gastrointestinal tract

Species : Mouse  
NOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 18 Months  
Target Organs : Blood, Cardio-vascular system

### Cellulose:

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

### Magnesium stearate:

Species : Rat  
NOAEL :  $> 100$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Ribavirin:

Inhalation : Symptoms: Headache, Dizziness  
Remarks: Based on Human Evidence  
Skin contact : Remarks: May cause eye irritation.  
Based on Human Evidence  
Eye contact : Remarks: May cause eye irritation.  
Based on Human Evidence  
Ingestion : Symptoms: blood effects, immune system effects, anorexia,  
Dizziness, insomnia, Fatigue, Headache, Itching, Rash, liver  
function change, Gastrointestinal disturbance

---

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### Ribavirin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)):  $> 119$  mg/l  
Exposure time: 96 h  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)):  $> 117$  mg/l  
Exposure time: 48 h

---

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 ( Pseudokirchneriella subcapitata (green algae)): > 119 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

NOEC ( Pseudokirchneriella subcapitata (green algae)): 6.9 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

### Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EL50 ( Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility

NOELR ( Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction

## Ribavirin Solid Formulation

Version 3.1      Revision Date: 30.09.2023      SDS Number: 413002-00019      Date of last issue: 04.04.2023  
Date of first issue: 11.12.2015

---

Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Magnesium stearate:**

Biodegradability : Result: Not biodegradable  
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

##### **Ribavirin:**

Partition coefficient: n-octanol/water : log Pow: 0.971

##### **Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

---

## 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

## 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	413002-00019	Date of first issue: 11.12.2015

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

## 16. OTHER INFORMATION

Revision Date : 30.09.2023

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Ribavirin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	413002-00019	Date of first issue: 11.12.2015

---

Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN